

OK TO ENTER
TM 2/4/04

AMENDMENTS TO THE CLAIMS:

This listing will replace all prior versions, and listings, of claims in the application.

LISTING OF CLAIMS:

1-3. (Canceled).

2 ~~A~~. (Currently Amended) A capsule as claimed in claim ~~68~~¹, wherein the ~~SAME~~ S-adenosylmethionine salt is present in an amount ranging from 425 mg to 440 mg.

3 ~~5~~. (Previously Presented) A capsule as claimed in claim ~~68~~¹ wherein the lipophilic material coated over the S-adenosylmethionine salt is selected from the group consisting of stearic acid, carnuaba wax, beeswax, polyoxyethylene sorbitan monoolcate, cetyl alcohol, glyceryl monostearate, cetostearyl alcohol and glyceryl behanate.

4 ~~6~~. (Previously Presented) A capsule as claimed in claim ~~68~~¹ wherein the lipophilic material is diluted with dichloromethane or isopropyl alcohol.

5 ~~A~~. (Previously Presented) A capsule as claimed in claim ~~68~~¹ wherein the amount of lipophilic material is 15 to 20% of the total fill material.

7 ~~8~~. (Currently Amended) A capsule as claimed in claim ~~68~~¹ wherein the ratio of lipophilic material to ~~SAME~~ S-adenosylmethionine salt is 5:1.

8/9. (Previously Presented) A capsule as claimed in claim 68 wherein the oil in the oily matrix is selected from the group consisting of soya bean oil, arachis oil, wheat germ oil, gel oil, corn oil, rice bran oil and mixtures thereof.

9/10. (Previously Presented) A capsule as claimed in claim 68 wherein the amount of oil is 50 to 55% w/w of the total fill material.

11. (Currently Amended) A capsule as claimed in claim 68 wherein the antioxidants are selected from the group consisting of citric acid, ascorbic acid, butylated ~~hydroxy-toulene~~ NDGA hydroxytoluene, butylated ~~hydroxy-anisole~~ hydroxyanisole and mixtures thereof.

12. (Previously Presented) A capsule as claimed in claim 68 wherein the amount of antioxidants is 0.1% w/w of the total fill material.

13. (Previously Presented) A capsule as claimed in claim 68 wherein the preservatives are selected from the group consisting of methyl paraben, propyl paraben and mixtures thereof.

14. (Previously Presented) A capsule as claimed in claim 68 wherein the soft gelatin film comprises softening agents, plasticizers, opacifying agents, preservatives and coloring agents.

15. (Original) A capsule as claimed in claim 14, wherein the gelatin present in the film is from 40 to 60% w/w.

16. (Previously Presented) A capsule as claimed in claim 14 wherein the softening agent is selected from the group consisting of glycerol, glycerine, triacetin, sorbitol, sorbitan anhydrides and mannitol.

17. (Previously Presented) A capsule as claimed in claim 14 wherein the amount of softening agent is 10% to 15% w/w of the gelatin content.

18. (Previously Presented) A capsule as claimed in claim 14 wherein the plasticizer is polyethylene glycol.

19. (Previously Presented) A capsule as claimed in claim 14 wherein the amount of plasticizer is about 25 to 30% w/w of the gelatin content.

20. (Previously Presented) A capsule as claimed in claim 14 wherein the opacifier is titanium dioxide.

21. (Previously Presented) A capsule as claimed in claim 14 wherein the opacifier is present in an amount of 0.2 to 0.5% w/w of the gelatin content.

22. (Previously Presented) A capsule as claimed in claim 14 wherein the coloring agent is iron oxide yellow.

23. (Previously Presented) A capsule as claimed in claim 14 wherein the amount of coloring agent present is 0.25%w/w of the gelatin content.

24. (Previously Presented) A capsule as claimed in claim 14 wherein the preservative is methyl paraben or propyl paraben.

25. (Previously Presented) A capsule as claimed in claim 14 wherein the amount of preservatives is 0.2 to 0.5% w/w of the gelatin content.

26. (Previously Presented) A capsule as claimed in claim ^l~~68~~ wherein the soft gelatin capsule is enteric coated with a coating agent selected from the group consisting of hydroxypropylmethyl cellulose phthalate (HPMCP), hydroxypropylmethyl cellulose succinate (HPMCS), carboxymethyl cellulose (CMEC) and methylacrylic acid copolymer.

27. (Previously Presented) A capsule as claimed in claim ^l~~68~~ wherein the thickness of the soft gelatin film ranges from about 0.9 to 1.1 mm.

28. (Previously Presented) A capsule as claimed in claim ^l~~68~~, wherein the enteric coating sustains a pH of 5.5 to 6.8.

29. (Canceled).

¹
~~29~~ ³⁰. (Currently Amended) A capsule as claimed in claim ~~68~~, wherein the enteric coating provides release of the ~~SAMe~~ S-adenosylmethionine salt within 2 hours of oral administration.

31-34. (Canceled).

~~30~~ ³⁵. (Currently Amended) A method of preparing an enteric-coated soft gelatin capsule comprising a core of ~~SAMe~~ S-adenosylmethionine salt selected from the group consisting of a ~~SAMe~~ S-adenosylmethionine monosulphate tosylate salt and a ~~SAMe~~ S-adenosylmethionine disulphate tosylate salt, said method comprising the steps of:

- a. coating the ~~SAMe~~ S-adenosylmethionine salt with a lipophilic material to obtain granules,
- b. ~~coating~~ mixing the granules obtained in step (a) with an oily matrix, antioxidants and preservatives to form a lipid suspension,
- c. disposing the lipid suspension in a soft gelatin film, and
- d. coating the soft gelatin film to obtain an enteric-coated soft gelatin capsule.

36-67. (Canceled).

¹ 68. (Currently Amended) An enteric-coated soft gelatin capsule with fill material comprising a core of SAME S-adenosylmethionine salt selected from the group consisting of a SAME S-adenosylmethionine monosulphate tosylate salt and a SAME S-adenosylmethionine disulphate tosylate salt, said salt being coated with lipophilic material, an oily matrix, antioxidants and preservatives, said fill material being disposed within a soft gelatin film.

⁵
⁶ 69. (Previously Presented) A capsule as claimed in claim ⁵ 67, wherein the amount of lipophilic material is 16% of the total fill material.

⁹
¹⁰ 70. (Previously Presented) A capsule as claimed in claim ⁹ 69, wherein the amount of oil is 53% w/w of the total fill material.